K122763

JUN 2 0 2013

5. 510(k) Summary

(per 21 CFR 807.92)

19 June 2013

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Proprietary Name:	Packet Decoder Process (PDP)
Common Name:	PDP
Device Classification Name:	Transmitters and receivers, physiological signal, radiofrequency
Classification Number:	21 CFR 870.2190
Product Code	DRG
Reviewing Group	Cardiovascular
Device Classification	Class II
Establishment registration No.	# 233836
Predicate Device	PDP is substantially equivalent to three predicates determined substantially Equivalent in K113045, BioHarness 3. 1) Firmware (9500.0085). The PDP is a mirror image of the portion of the firmware (PEP) that implements the encoding of digital data. 2) Test Application (9500.0091). The PDP performs the same function as the Test Application to decode packet data and places the decoded data in registers for MDDS access. 3) Config Tool (9500.0096). The PDP performs the same features / functions as the Config Tool (9500.0096) to change threshold alert settings in the hardware resisters in the BioHarness 3.

Device Description

The Packet Decoder Process (PDP) receives digital data that is transmitted by ***BioHarness 3.0***, K113045 in a proprietary structure. PDP receives this complex array of packet coded data. A decoding scheme is used to decode data and organize for presentation and access by Class I MDDS devices.

The Packet Decoder Process is manufactured by Zephyr Technology Corporation. This software is loaded and executed in an MDDS operating systems in an MDDS computer. This complex process is defined by a proprietary scheme: Zephyr's General Comms Link Specification.

INDICATIONS FOR USE

The Packet Decoder Process (PDP) is indicated for use as a prescription software device to receive MDDS digital data packets and decode, collate and deliver data to a Class I, MDDS, Enterprise Service Bus according to a proprietary scheme defined by Zephyr Technology.

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(per 21 CFR 807.92)

INTENDED USE

The BioHarness 3-M1 Packet Decoder Process (PDP) is intended for decoding digital data packets that were coded in the BioHarness 3.0 Packet Encoder Processor (PEP). The decoding process receives data from an MDDS data transmission system then decodes, collates and drives MDDS registers on the Enterprise Service Bus. This process is defined by the proprietary scheme: Zephyr's General Comms Link Specification, version 1.44 dated 11 June 2009 Part Number #9700.0028 (and subsequent revisions).

The **scientific concept** on which this device is based is the principle that complexity and precise structure of packet data give rise to a repeatable mechanism to "pack up" digital data and transmit it using a qualified communication system. At the receive side, a scheme decodes or "un-pack" this data and delivers it to MDDS registers. This device **functions** by executing programmed commands written in the Java language. The calibration is established by the factory and yields accurate and calibrated signals that can maintain calibration over its useful life.

Substantial Equivalence

Zephyr Technology Corporation has determined that the Packet Decoder Process (PDP) is substantially equivalent to the performance to the predicate device. The differences between these systems are incidental and not significant. Both this device and the predicates use a similar technological characteristics and principles.

Safety and Effectiveness

This device is safe and effective for the application for which it is intended and has been tested to confirm safety and efficacy. A series of factory tests are conducted to verify the intended signals are accurate and can maintain calibration over its useful life. The Packet Decoder Process (PDP) has benefited from design, development, testing and production procedures that conform to Quality Systems.

Zephyr Technology Corporation continues to search all appropriate sources for information relating to safety and effectiveness and maintains an *in-house* reporting device to identify adverse safety and effectiveness information and as such, applicable data is recorded for this product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 20, 2013

Zephyr Technology Corp.
c/o Richard Keen
1151 Hope St
Stamford, CT 06907

Re: K122763
Trade/Device Name: Packet Decoder Process (PDP)
Regulation Number: 21 CFR 870.2190
Regulation Name: Transmitters and receivers, physiological signal, radiofrequency
Regulatory Class: Class II
Product Code: DRG
Dated: February 18, 2013
Received: April 25, 2013

Dear Mr. Keen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(K) Number assigned K 122763 Name: *Packet Decoder Process (PDP)*

INDICATIONS FOR USE

The Packet Decoder Process (PDP) is indicated for use as a prescription software device to receive MDDS digital data packets and decode, collate and deliver data to a Class I, MDDS, Enterprise Service Bus according to a proprietary scheme defined by Zephyr Technology.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)		
Prescription Use **___XXX____**	**or**	**Over - The - Counter Use** **(Per 21 CFR 801.109)**
		(Optional Format 1-2-96

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
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